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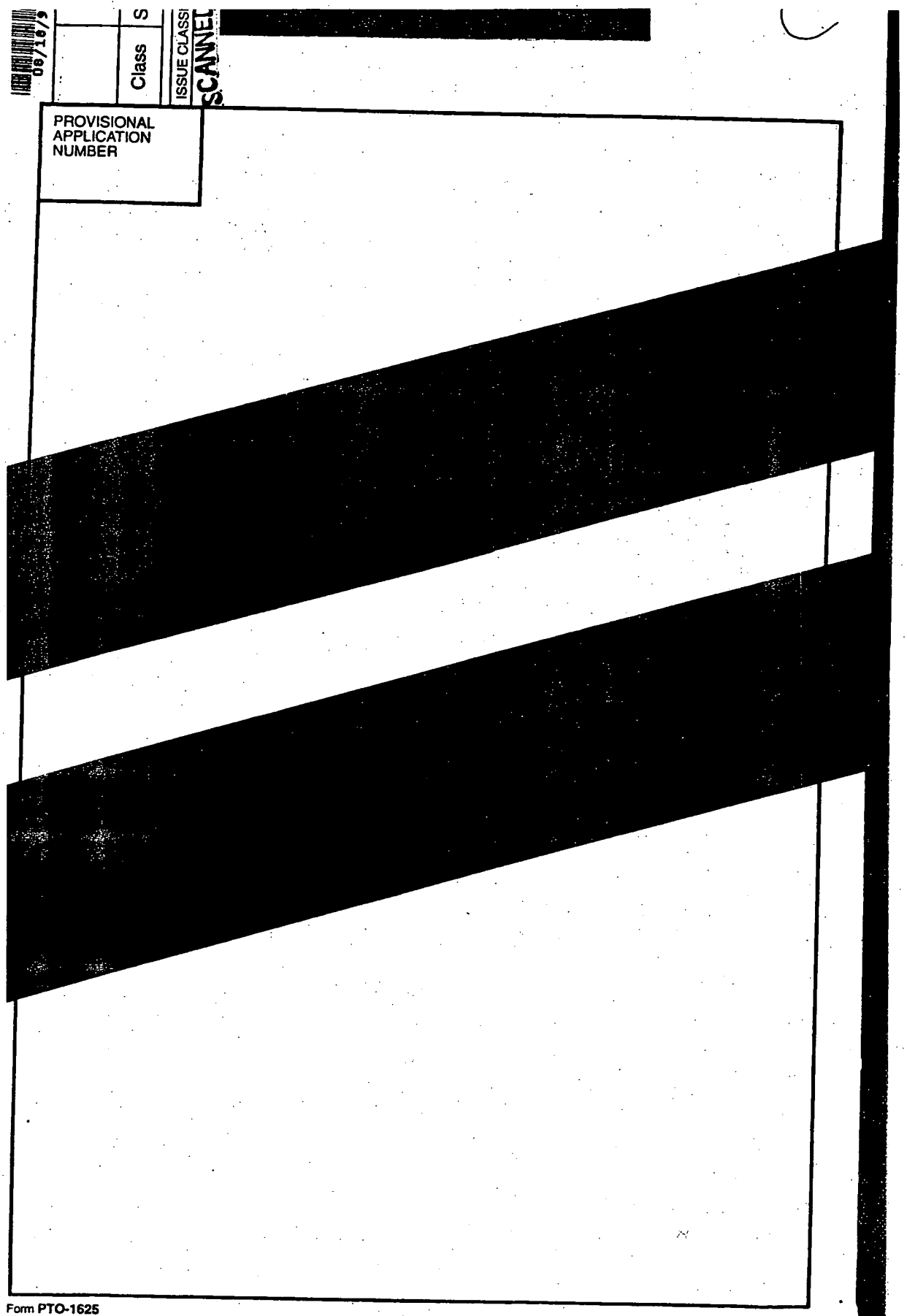

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PATENT APPLICATION SERIAL NO. 60-149490

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08/23/1999 ASAHLE 00000007 60149490
01 FC:214 75.00 OP

PTO-1556
(5/87)
*U.S. GPO: 1998-433-214/80404

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
60/149,490 PROVISIONAL	08/18/99		0000	LAML-110PR

APPLICANT

GREGORY H. LAMBRECHT, NATICK, MA.

CONTINUING DOMESTIC DATA********
VERIFIED

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371 (NAT'L STAGE) DATA********
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FOREIGN APPLICATIONS********
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Foreign Priority claimed 35 USC 119 (a-d) conditions met Verified and Acknowledged	☐yes ☐no ☐yes ☐no ☐Met after Allowance Examiner's Initials _____ Initials	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MA	12		

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TITLE

DEVICES AND METHODS OF INTERVERTEBRAL DISC AUGMENTATION

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Docket Number: LAML-110PR

PROVISIONAL APPLICATION FOR PATENT COVER SHEET (Small Entity)

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Gregory H.	LAMBRECHT	220 Eliot Street, Natick, MA 01760

☐ *Additional inventors are being named on page 2 attached hereto*

TITLE OF THE INVENTION (280 characters max)

DEVICES AND METHODS OF INTERVERTEBRAL DISC AUGMENTATION

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*

OR

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification — *Number of Pages* 23 — ☒ Small Entity Statement

☒ Drawing(s) — *Number of Sheets* 12 — ☒ Other (specify) Return postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____ Date August 18, 1999

TYPED or PRINTED NAME Mark G. Lappin REGISTRATION NO. *(if appropriate)* 26,618

TELEPHONE 617-330-1300

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P19SMALL/REV04

Docket Number:	LAML-110PR

PROVISIONAL APPLICATION FOR PATENT COVER SHEET (Small Entity)

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (city and either State or Foreign Country)

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LAML-110PR

APPLICATION

FOR

UNITED STATES LETTERS PATENT

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Gregory H. Lambrecht, a U.S. citizen, residing in Natick, MA, has invented certain improvements in DEVICES AND METHODS OF INTERVERTEBRAL DISC AUGMENTATION of which the following description in connection with the accompanying drawings is a specification, like reference characters on the drawings indicating like parts in the several figures.

Devices and Methods of Intervertebral Disc Augmentation

Field of the Invention

The present invention relates to the surgical treatment of intervertebral (IV) discs in the lumbar, cervical, or thoracic spine that have either suffered from herniation or significant disc height loss.

Background

Herniation of an IV disc is one of the ten most common diagnoses in the United States. The disc performs the important role of absorbing mechanical loads while allowing for constrained flexibility of the spine. The disc is composed of a soft, central nucleus pulposus (NP) surrounded by a tough, woven anulus fibrosis (AF). Herniation is a result of a weakening in the AF. Symptomatic herniations occur when weakness in the AF allows the NP to bulge or leak posteriorly toward the spinal cord and major nerve roots. The most common resulting symptoms are pain radiating along a compressed nerve and low back pain, both of which can be crippling for the patient. The significance of this problem is increased by the low average age of diagnosis, with over 80% of patients in the U.S. being under age 59.

Since its original description by Mixter & Barr in 1934, (Mixter and Barr, 1934, New Engl J Med, 211:210-215) discectomy has been the most common surgical procedure for treating IV disc herniation. This procedure involves removal of disc materials impinging on the nerve roots or spinal cord posterior to the disc. Depending on the surgeon's preference, varying amounts of NP is then removed from within the disc space either through the herniation site or through a surgical incision in the AF. This removal of extra NP is commonly done to minimize the risk of recurrent herniation.

Nevertheless, the most significant drawbacks of discectomy are recurrence of herniation, recurrence of radicular symptoms, and increasing low back pain. Re-herniation can occur in up to 21% of cases. The site for re-herniation is most commonly

the same level and side as the previous herniation and can occur through the same weakened site in the AF. Persistence or recurrence of radicular symptoms happens in many patients and when not related to re-herniation, tends to be linked to stenosis of the neural foramina caused by a loss in height of the operated disc. Debilitating low back pain occurs in roughly 14% of patients. All of these failings are most directly related to the loss of NP material and AF competence that results from herniation and surgery.

Loss of NP material deflates the disc, causing a decrease in disc height. Significant decreases in disc height have been noted in up to 98% of operated patients. Loss of disc height increases loading on the facet joints. This can result in deterioration of facet cartilage and ultimately osteoarthritis and pain in this joint. As the joint space decreases the neural foramina formed by the inferior and superior vertebral pedicles also close down. This leads to canal stenosis, pinching of the traversing nerve root, and recurring radicular pain. Loss of NP also increases loading on the remaining AF, an innervated structure that can produce pain. Finally, loss of NP results in greater bulging of the AF under load. This can result in renewed impingement by the AF on nerve structures posterior to the disc.

Persisting tears in the AF that result either from herniation or surgical incision also contribute to poor results from discectomy. The AF has been shown to have limited healing capacity with the greatest healing occurring in its outer borders. Healing takes the form of a thin fibrous film that does not approach the strength of the uninjured disc. Surgical incision in the AF has been shown to produce immediate and long lasting decreases in stiffness of the AF particularly against torsional loads. This may over-stress the facets and contribute to their deterioration. Further, in as many as 30% of cases, the AF never closes. In these cases, not only is re-herniation a risk but also leakage of fluids from within the NP into the epidural space can occur. This has been shown to cause localized pain, irritation of spinal nerve roots, decreases in nerve conduction velocity, and may contribute to the formation of post-surgical scar tissue in the epidural space. To date, there have been very few attempts to repair the IV disc. Yasargil (Yasgaril,1984, Advances and Technical Standards in Microsurgery, 7:18) mentions suturing the AF closed after complete removal of the NP, but does nothing to limit disc height loss or posterior bulging of the AF.

Other orthopedic procedures involving removal of soft tissue from a joint to relieve pain have resulted in significant, long lasting consequences. Removal of all or part of the menisci of the knee is one example. Partial and total meniscectomy leads to increased osteoarthritic degeneration in the knee and the need for further surgery in many patients. A major effort among surgeons to repair rather than resect torn menisci has resulted in more durable results and lessened joint deterioration. US Patent No. 5,500,000 issued to Feagin at al. (the '000 patent) discloses a system and method for repairing tears in soft tissues. The system is limited to a barbed tissue anchor, an attached length of suture, and a suture-retaining member, which can be affixed to the suture and used to draw the sides of a tear into apposition. The drawback of this method is that it is limited to the repair of a tear in soft tissue. In the IV disc, closure of a tear in the AF does not necessarily prevent further bulging of that disc segment toward the posterior neural elements. Further, there is often no apparent tear in the AF when herniation occurs. Herniation can be a result of a general weakening in the structure of the AF (soft disc) that allows it to bulge posteriorly without a rupture. When tears do occur, they are often radial. Placing an anchor across such a tear plane as disclosed in the '000 patent would require medial-lateral placement of the anchor. The limited exposure provided by the posterior elements of the vertebrae and the orientation of the tissue planes and fibers of the AF make this invention very difficult to implant in the disc and of questionable therapeutic benefit. The '000 patent further does not disclose any augmentation of the injured soft tissue.

US Patent No. 5,702,462 issued to Oberlander (the '462 patent) has all of the limitations of the '000 patent. The disclosed invention is intended for repair of a tear in a previously contiguous soft tissue. Dart anchors are placed across the tear in a direction generally perpendicular to the plane of the tear. Sutures leading from each of at least two anchors are then tied together such that the opposing sides of the tear are brought together.

Two related patents, US 5,556,428 and 5,769,893, both issued to Shah, (the '428 and '893 patents) disclose an apparatus and method of using tension to induce growth of soft tissue. The disclosed embodiments and methods are limited in their application to hernias of the IV disc in that they require a spring to apply tension. Aside from the

difficulty of placing a spring within the limited space of the IV disc, a spring will induce a continuous displacement of the attached tissues that could be deleterious to the structure and function of the disc. A spring may further allow a posterior bulge in the disc to progress should forces within the disc exceed the tension force applied by the spring. Further, the disclosed invention is designed to be removed once the desired tissue growth has been achieved. This has the drawback of requiring a second procedure.

There are numerous ways of augmenting the IV disc disclosed in the art. In reviewing the art, two general approaches are apparent – implants that are fixed to surrounding tissues and those that are not fixed, relying in stead on the AF to keep them in place.

The first type generally replace the entire disk, such as US Patent No. 3,867,728 issued to Stubstad, US Patent No. 4,932,966 issued to Frey, and US Patent No. 5,108,438 issued to Stone. These concepts are limited in many ways. First, by replacing the entire disc they generally must endure all of the loads that are transferred through that disc space. Many degenerated discs are subject to pathologic loads that exceed those in normal discs. Hence, the designs must be extremely robust and yet flexible. None of these devices has yet been able to achieve both qualities. Further, devices that replace the entire disc must be implanted using relatively invasive procedures, normally from an anterior approach. They may also require the removal of considerable amounts of healthy disc material including the anterior AF. Further, the disclosed inventions must account for the contour of the neighboring vertebral bodies to which they are attached. Because each patient and each vertebra is different, these types of implants must be available in many sizes.

The second type of augmentation involves an implant that is not directly fixed to surrounding tissues. Examples include US Patent No.5,824,093 issued to Ray, US Patent No.5,888,220 issued to Felt, US Patent No.5,645,597 issued to Krapiva, US Patent No. 5,047,055 and US 5,192,326, both issued to Bao, and Baumgertner's series of patents: US Patent Nos. 5,702,454, and 5,171280, and patent publications EP 0621020A1, and EP 0453393A1. These inventions rely on an AF that is primarily intact to hold them in place. The disclosed implants are generally inserted through a hole in the AF and either expand, are inflated, or deploy expanding elements so as to be larger than hole through

which they are inserted. The limitation of these concepts is that the AF is often not intact in cases requiring augmentation of the disc. There are either rents in the AF or structural weaknesses that would allow herniation or migration of the disclosed implants. In the case of a disc herniation, there are definite weaknesses in the AF that allowed the herniation to occur. Augmenting the NP with any of the above disclosed inventions without supporting the AF or implant risks re-herniation of the augmenting materials. Further, those inventions with deployable elements such as the '093 patent and the '454 patent risk injuring the vertebral endplates or the AF indiscriminately. Many of the patents describe closing the AF at the site of insertion. This may help, but again herniations do not require a rent in the AF. Structural weakness in or delamination of the multiple layers of the AF can allow these implants to bulge toward the posterior neural elements. Additionally, as the disc continues to degenerate, rents in the posterior anulus may occur in regions other than the original operated site. A further limitation of these concepts is that they require the removal of much or all of the NP to allow insertion of the implant. This requires time and skill to achieve and may permanently alter the physiology of the disc.

It is the object of the disclosed invention to overcome the many limitations of the described devices. Repairing a tear in the AF can accompany this method, but is not necessary for achieving the purpose of the disclosed invention. It is a further object of this invention to reduce the long-term negative consequences of herniated discs by repairing and/or augmenting rather than resecting the soft tissues of the disc. It is a further object of this invention to prevent or reduce the occurrence of re-herniation and disc height loss following surgical therapy for herniated IV discs. It is a further object of this invention to increase the AF's resistance to posterior bulging and leakage of NP material while increasing its stiffness under load. It is a further object of this invention to permit the augmentation of the soft tissues of the disc in such a way so as to limit the risk of the herniation of any augmentation materials toward nerve structures posterior to the disc.

Summary of the Invention

In one aspect of the present invention there is provided an *in vivo* augmented functional spine unit. The augmented functional spine unit includes the two adjoining vertebra and the intervertebral disc, composed of a central region surrounded by an anterior fibrosis and situated in the intervertebral disc space between the vertebra, and a disc herniation constraining device situated within the intervertebral disc space. A disc herniation constraining device includes an anchor fixedly coupled to an anterior portion of one of the adjoining vertebra or anterior fibrosis and is connected to a support member by a connecting member. The support member is positioned posterior to the central region, preferably in or posterior to the anulus fibrosis. In one embodiment the central region of the functional spine unit contains a nucleus pulposus. In another embodiment of the invention, the connection member is maintained under tension between the anchor and the support member. In yet another embodiment, augmentation material is secured along at least a portion of the length of the connection member, which serves to assist the function of the intervertebral disk in supporting and separating the vertebrae, and allowing motion of one vertebra relative to the other.

In another aspect of the invention there is provided an in vivo augmented functional spine unit. The augmented functional spine unit includes the two adjoining vertebra and the intervertebral disc, composed of a central region surrounded by an anulus fibrosis and situated in the intervertebral disc space between the vertebra, and a disc augmentation device situated within the intervertebral disc space. The disc augmentation device includes an anchor fixedly coupled to an anterior portion of one of the adjoining vertebra or anulus fibrosis, augmentation material situated in the intervertebral disc space and restrained therein by a connection member secured between the anchor and the augmentation material. In an alternate embodiment, a support member is secured within the functional spine unit, the connection member extends between the anchor, the augmentation material and the support member, further restraining the movement of the augmentation material within the central region. In yet another embodiment, the central region may contain a nucleus pulposus.

In yet another aspect of the present invention there are provided methods of augmenting a functional spine unit. These methods include using the disc herniation constraining devices and the disc augmentation devices disclosed herein.

Brief Description of the Drawings

The foregoing and other objects of the invention, the various features thereof, as well as the invention itself, may be more fully understood from the following description, when read together with the accompanying drawings, in which:

Fig. 1A shows an axial view of a portion of a functional spine unit, in which part of a vertebra and intervertebral disc are depicted;

Fig. 1b shows an sagittal cross section of a portion of a functional spine unit shown in Figure 1A, in which two lumbar vertebrae and the intervertebral disc are visible;

Fig. 2A shows an axial view of one aspect of the invention showing a portion of the FSU prior to supporting a herniated segment;

Fig. 2B shows an axial view of the construct in Fig. 2A supporting the herniated segment;

Fig. 3a shows an axial view of another embodiment of the disclosed invention after placement of the device;

Fig. 3B shows an axial view of the construct in Fig. 3a after tension is applied to support the herniated segment;

Fig. 4A shows an axial view of an alternate embodiment of the invention;

Fig. 4B shows a sagittal view of the alternate embodiment shown in Fig, 4A;

Fig. 5A shows an axial view of another aspect of the present invention.

Fig. 5B shows the delivery tube of Fig. 5A being used to displace the herniated segment to within its pre-herniated borders;

Fig. 5C shows a one piece embodiment of the invention in an anchored and supporting position;

Fig. 6 shows one embodiment of the invention supporting a weakened posterior anulus fibrosis;

Fig. 7A shows an axial view of another aspect of the disclosed invention demonstrating two stages involved in augmentation of the soft tissues of the disc;

Fig. 7B shows a sagittal view of the invention shown in Fig, 7A;

Fig. 8 shows an axial view of one aspect of the disclosed invention involving augmentation of the soft tissues of the disc and support/closure of the anulus fibrosis;

Fig. 9A shows an axial view of one aspect of the invention involving augmentation of the soft tissues of the disc with the flexible augmentation material anchored to the anterior lateral anulus fibrosis;

Fig. 9B shows an axial view of one aspect of the disclosed invention involving augmentation of the soft tissues of the disc with the flexible augmentation material anchored to the anulus fibrosis by a one piece anchor;

Fig. 10A shows an axial view of one aspect of the disclosed invention involving augmentation of the soft tissues of the disc; and

Fig. 10B shows the construct of Fig. 10A after the augmentation material has been inserted into the disc.

Description of the Preferred Embodiments

The present invention provides for an in vivo augmented functional spine unit. A functional spine unit includes the bony structures of two adjacent vertebrae (or vertebral bodies), the soft tissue (anulus fibrosis (AF), and optionally nucleus pulposus (NP)) of the intervertebral disc, and the ligaments, musculature and connective tissue connected to the vertebrae. The intervertebral disc is substantially situated in the intervertebral space formed between the adjacent vertebrae. Augmentation of the functional spine unit can include repair of a herniated disc segment, support of a weakened, torn or damaged anulus fibrosis, or the addition of material to or replacement of all or part of the nucleus pulposus. Augmentation of the functional spine unit is provided by herniation constraining devices and disc augmentation devices situated in the intervertebral disc space.

Figures 1A and 1B show the general anatomy of a functional spine unit 45. In this description and the following claims, the terms 'anterior' and 'posterior', 'superior' and 'inferior' are defined by their standard usage in anatomy, i.e., anterior is a direction toward the front (ventral) side of the body or organ, posterior is a direction toward the back (dorsal) side of the body or organ; superior is upward toward the head and inferior is lower or toward the feet.

Figure 1A is an axial view (transverse) along transverse axis M of a vertebral body with the intervertebral disc15 superior to the vertebral body. Axis M shows the anterior (A) and posterior (P) orientation of the functional spine unit within the anatomy. The intervertebral disc 15 contains the anulus fibrosis (AF) 10 which surrounds a central nucleus pulposus (NP) 20. Herniated segment 30 is depicted by a dashed-line. Herniated segment 30 protrudes beyond the pre-herniated posterior border 40 of the disc. Also shown in this figure are the left 70 and right 70' transverse spinus processes and the posterior spinus process 80.

Figure 1B is a sagittal section along sagittal axis N through the midline of two adjacent vertebral bodies 50 (superior) and 50'(inferior). Intervertebral disc space 55 is formed between the two vertebral bodies and contains intervertebral disc 15, which supports and cushions the vertebral bodies and permits movement of the two vertebral bodies with respect to each other and other adjacent functional spine units. Intervertebral disc 15 is comprised of the outer AF 10 which normally surrounds and constrains the NP 20 to be wholly within the borders of the intervertebral disc space. In Figs. 1A and 1B, herniated segment 30, represented by the dashed-line, has migrated posterior to the pre-herniated border 40 of the posterior AF of the disc. Axis M extends between the anterior (A) and posterior (P) of the functional spine unit. The vertebral bodies also include facet joints 60 and the superior 90 and inferior 90' pedicle that form the neural foramen 100. Disc height loss occurs when the superior vertebral body 50 moves inferiorly relative to the inferior vertebral body 50'.

In one embodiment of the present invention, the disc herniation constraining devices provide support for returning all or part of the herniated segment 30 to a position substantially within its pre-herniated borders 40. The disc herniation constraining device includes an anchor which is positioned at a site within the functional spine unit, such as the superior or inferior vertebral body, or the anterior, medial, or anterior lateral anulus fibrosis. The anchor is used as a point against which all or part of the herniated segment is tensioned so as to return the herniated segment to its pre-herniated borders, and thereby relieve pressure on otherwise compressed neural tissue and structures. A support member is positioned in or posterior to the herniated segment, and is connected to the anchor by a connecting member. Sufficient tension is applied to the connecting member

so that the support member returns the herniated segment to a pre-herniated position. In various embodiments, augmentation material is secured within the intervertebral disc space, which provides assists the NP in cushioning and supporting the inferior and superior vertebral bodies. An anchor secured in a portion of the functional spine unit and attached to connection member and augmentation material, limits movement of the augmentation material within the intervertebral disk space. A supporting member, located opposite the anchor, may optionally provide a second point of attachment for the connecting member and further hinder the movement of the augmentation material within the intervertebral disk space.

Figures 2A and 2B depict one embodiment of device 12. Figure 2A shows the elements of the constraining device in position to correct the herniated segment. Anchor 1 is securely established in a location within the functional spine unit, such as the anterior AF shown in the figure. Support member 2 is positioned in or posterior to herniated segment 30. Leading from and connected to anchor 1 is connection member 3, which serves to connect anchor 1 to support member 2. Depending on the location chosen for support member 2, the connection member may traverse through all or part of the herniated segment.

Figure 2B shows the positions of the various elements of the herniation constraining device when the device is supporting the herniating segment. Tightening connection member 2 allows it to transmit tensile forces along its length, which causes herniated segment 30 to move anteriorly, i.e., in the direction of its pre-herniated borders. Once herniated segment 30 is in the desired position, connection member 3 is secured in a permanent fashion between anchor 1 and support member 2. This maintains tension between anchor 1 and support member 2 and restricts motion of the herniated segment to within the pre-herniated borders 40 of the disc. Support member 2 is used to anchor to herniated segment 30, support a weakened AF in which no visual evidence of herniation is apparent, and it may also be used to close a defect in the AF of herniated segment 30.

Anchor 1 is depicted in a representative form because it can take one of many forms, be made from one of a variety of biocompatible materials, and be constructed so as to have one of a range of stiffness. It can be a permanent device constructed of

durable plastic or metal or can be made from a resorbable material such as polylactic acid (PLA) or polyglycolic acid (PGA). Specific embodiments are not shown, but many possible designs would be obvious to anyone skilled in the art. Embodiments include, but are not limited to, a barbed anchor made of PLA or a metal coil that can be screwed into the anterior AF. Anchor 1 can be securely established within a portion of the functional spine unit in the usual and customary manner for such devices and locations, such as being screwed into bone, sutured into tissue or bone, or affixed to tissue or bone using an adhesive method, such as cement, and suitable surgical adhesives. Once established within the bone or tissue, anchor 1 should remain relatively stationary within the bone or tissue.

Support member 2 is also depicted in a representative format and shares the same flexibility in material and design as anchor 1. Both device elements can be of the same design, or they can be of different designs, each better suited to being established in healthy and diseased tissue respectively. Alternatively, in other forms, support member 2 can be a cap or a bead shape, which also serves to secure a tear or puncture in the AF, or it can be bar or plate shaped, with or without barbs to maintain secure contact with the herniated segment. Support member 2 can be established securely to, within, or posterior to the herniated segment.

The anchor and support member can include suture, bone anchors, soft tissue anchors, tissue adhesives, and materials that support tissue ingrowth although other forms and materials are possible. They may be permanent devices or resorbable. Their attachment to a portion of FSU and herniated segment must be strong enough to resist the tensional forces that result from repair of the hernia and the loads generated during daily activities.

Connection member 3 is also depicted in representative fashion. Member 3 may be in the format of a flexible filament, such as a single or multi-strand suture, wire, or maybe a rigid rod or broad band of material, for example. The connection member can further include suture, wire, pins, and woven tubes or webs of material. It can be constructed from a variety of materials, either permanent or resorbable, and can be of any shape suitable to fit within the confines of the intervertebral disc space. The material chosen is preferably adapted to be relatively stiff while in tension, and relatively flexible

against all other loads. This allows for maximal mobility of the herniated segment relative to the anchor without the risk of the supported segment moving outside of the pre-herniated borders of the disc. The connection member may be an integral component of either the anchor or support member or a separate component. For example, the connection member and support member could be a length of non-resorbing suture that is coupled to an anchor, and tensioned against the anchor, and sewn to the herniated segment.

Figures 3A and 3B depict another embodiment of device 12. In Figure 3A the elements of the herniation constraining device are shown in position prior to securing a herniated segment. Anchor 1 is positioned in the AF, and connection member 3 is attached to anchor 1. Support member 4 is positioned posterior to the posteriormost aspect of herniated segment 30. In this way, support member 4 does not need to be secured in herniated segment 30 to cause herniated segment 30 to move within the pre-herniated borders 40 of the disc. Support member 4 has the same flexibility in design and material as anchor 1, and may further take the form of a flexible patch or rigid plate or bar of material that is either affixed to the posterior aspect of herniated segment 30 or is simply in a form that is larger than any hole in the AF directly anterior to support member 4. Figure 3B shows the positions of the elements of the device when tension is applied between anchor 1 and support member 4 along connection member 3. The herniated segment is displaced anteriorly, within the pre-herniated borders 40 of the disc.

Figures 4A and 4B show five examples of suitable anchoring sites within the FSU for anchor 1. Figure 4A shows an axial view of anchor 1 in various positions within the anterior and lateral AF. Figure 4B similarly shows a sagittal view of the various acceptable anchoring sites for anchor 1. Anchor 1 is secured in the superior vertebral body 50, inferior vertebral body 50' or anterior AF 10, although any site that can withstand the tension between anchor 1 and support member 2 along connection member 3 to support a herniated segment within its pre-herniated borders 40 is acceptable.

Generally, a suitable position for affixing one or more anchors is a location anterior to the herniated segment such that, when tension is applied along connection member 3, herniated segment 30 is returned to a site within the pre-herniated borders 40. The site chosen for the anchor should be able to withstand the tensile forces applied to

the anchor when the connection member is brought under tension. Because most symptomatic herniations occur in the posterior or posterior lateral directions, the preferable site for anchor placement is anterior to the site of the herniation.. Any portion of the involved FSU is generally acceptable, however the anterior, anterior medial, or anterior lateral AF is preferable. These portions of the AF have been shown to have considerably greater strength and stiffness than the posterior or posterior lateral portions of the AF. These portions of the AF are also more flexible than the superior and inferior vertebral bodies and will allow greater mobility of the supported herniated segment. As shown in Figures 4A and 4B, anchor 1 can be a single anchor in any of the shown locations, or there can be multiple anchors 1 affixed in various locations and connected to a support member 2 to support the herniated segment. Connection member 3 can be one continuous length that is threaded through all the sited anchors and the support member, or it can be several individually strands of material each terminated under tension between an anchor and one or more support members (not shown).

In various forms of the invention, the anchor(s) and connection member may be introduced and installed in the patient, with the connection member under tension. Alternatively, those elements may be installed, without introducing tension to the connection member, but where the connection member is adapted to be under tension when the patient is in a non-horizontal position, i.e., resulting from loading in the IV disc.

Figures 5A, B, and C show an alternate embodiment of herniation constraining device 12a. In this series of figures, device 12a, a substantially one-piece construct, is delivered through delivery a tube 6, although device 12a could be delivered in a variety of ways including, but not limited to, by hand or by a hand held grasping instrument. In Figure 5A, device 12a in delivery tube 6 is positioned against herniated segment 30. In Figure 5B, the herniated segment is displaced within its pre-herniated borders 40 by device 12a and/or delivery tube 6 such that when, in Figure 5C, device 12a has been delivered through delivery tube 6, and secured within a portion of the FSU, the device supports the displaced herniated segment within its pre-herniated border 40. Herniation constraining device 12a can be made of a variety of materials and have one of many possible forms so long as it allows support of the herniated segment 30 within the pre-

herniated borders 40 of the disc. Device 12a can anchor the herniated segment 30 to any suitable anchoring site within the FSU, including, but not limited to the superior vertebral body, inferior vertebral body, or anterior AF. Device 12a may be used additionally to close a defect in the AF of herniated segment 30. Alternatively, any such defect may be left open or may be closed using another means.

Figures 6 depicts the substantially one piece device 12a supporting a weakened segment 30' of the posterior AF 10'. Device 12a is positioned in or posterior to the weakened segment 30' and secured to a portion of the FSU, such as the superior vertebral body 50, shown in the figure, or the inferior vertebral body 50' or anterior, medial, anterior lateral anulus fibrosis 10. In certain patients, there may be no obvious herniation found at surgery. However, a weakened or torn AF that may not to be protruding beyond the pre-herniated borders of the disc may still induce the surgeon to remove all or part of the NP in order to decrease the risk of herniation. As an alternative to discectomy, any of the embodiments of the invention may be used to support and perhaps close defects in or weakened segments of AF.

A further embodiment of the present invention involves augmentation of the soft tissues of the intervertebral disc to avoid or reverse disc height loss. Figures 7A and 7B show one embodiment of device 12 securing augmentation material in the intervertebral disc space 55. In the left side of Figure 7A, anchors 1 have been established in the anterior AF 10. Augmentation material 7 is in the process of being inserted into the disc space along connection member 3 which, in this embodiment, has passageway 9. Support member 2' is shown ready to be attached to connection member 3 once the augmentation material 7 is properly situated. In this embodiment, connection member 3 passes through an aperture 11 in support member 2', although many other methods of affixing support member 2' to connection member 3 are possible and within the scope of this invention.

Augmentation material 7 may have a passageway 9, such as a channel, slit or the like, which allows it to slide along the connection member 3, or augmentation material 7 may be solid, and connection member 3 can be threaded through augmentation material by means such as needle or other puncturing type device. Connection member 3 is affixed at one end to anchor 1 and terminated at its other end by a support member 2', one

embodiment of which is shown in the figure in a cap-like configuration. Support member 2' can be affixed to connection member 3 in a variety of ways, including but not limited, to swaging support member 2' to connection member 3. In a preferred embodiment, support member 2' is in a cap configuration and has a dimension (diameter or length and width) larger than the optional passageway 9, which serves to prevent augmentation material 7 from displacing posteriorly with respect to anchor 1. The right half of the intervertebral disc of Figure 7A (in axial view) and figure 7B(in sagittal view) show augmentation material 7 that has been implanted into the disc space 55 along connection member 3 where it supports the vertebral bodies 50 and 50'. Figure 7A shows an embodiment in which support member 2' is affixed to connection member 3 and serves only to prevent augmentation material 7 from moving off connection member 3. The augmentation device is free to move within the disc space. Figure 7B shows an alternate embodiment in which support member 2' is embedded in a site in the functional spine unit, such as a herniated segment or posterior anulus fibrosis, to further restrict the movement of augmentation material 7 within the disc space.

Augmentation material can be made of any biocompatible, preferably flexible, material. Such a flexible material is preferably fibrous, like cellulose or bovine or autologous collagen. The augmentation material can be shaped like plugs, discs, cube-like, ellipsoid, spheroid or any other suitable shape.. The augmentation material can be secured within the intervertebral space by a variety of methods, such as but not limited to, a suture loop attached to, around, or through the material, which is then passed to the anchor and support member.

Figures 8, 9A, 9B and 10A and B depict further embodiments of the disc herniation constraining device 12b in use for augmenting soft tissue, particularly tissue within the intervertebral space. In the embodiments shown in Figures 8 and 9A, device 12b is secured within the intervertebral disc space providing additional support for NP 20. Anchor 1 is securely affixed in a portion of the FSU, (anterior AF 10 in these figures). Connection member 3 terminates at support member 2, preventing augmentation material 7 from migrating generally posteriorly with respect to anchor 1. Support member 2 is depicted in these figures as established in various locations, such as the posterior AF 10' in Figure 8, but support member 2 may be anchored in any suitable

location within the FSU, as described previously. Support member 2 may be used to close a defect in the posterior AF. It may also be used to displace a herniated segment to within the pre-herniated borders of the disc by applying tension between anchoring means 1 and 2 along connection member 3.

Figure 9A depicts anchor 1, connection member 3, augmentation material 7 and support member 2' (shown in the "cap"-type configuration) inserted as a single construct and anchored to a site within the disc space, such the inferior or superior vertebral bodies (not shown). This configuration simplifies insertion of the embodiments depicted in Figures 7 and 8 by reducing the number of steps to achieve implantation. Connection member 3 is preferably relatively stiff in tension, but flexible against all other loads. Support member 2' is depicted as a bar element that is larger than passageway 9 in at least one plane.

Figure 9B depicts a variation on the embodiment depicted in Figure 9A. Figure 9B shows substantially one piece disc augmentation device 12c, secured in the intervertebral disc space. Device 12c has anchor 1, connection member 3 and augmentation material 7. Augmentation material 7 and anchor 1 could be pre-assembled prior to insertion into the disc space 55 as a single construct. Alternatively, augmentation material 7 could be inserted first into the disc space and then anchored to a portion of the FSU by anchor 1.

Figures 10A and 10B show yet another embodiment of the disclosed invention, 12d. In this Figure 10A, two connection members 3 and 3' are attached to anchor 1. Two plugs of augmentation material 7 and 7' are inserted into the disc space along connection members 3 and 3'. Connection members 3 and 3' are then bound together (i.e, knotted together, fused or the like). This forms loop 3" that serves to prevent augmentation materials 7 and 7' from displacing posteriorly. Figure 10B shows the position of the augmentation material 7 after it is secured by the loop 3" and anchor 1. Various combinations of augmentation material, connecting members and anchors can be used in this embodiment, such as using a single plug of augmentation material, or two connection members leading from anchor 1 with each of the connection members being bound to at least one other connection member. It could further be accomplished with more than one anchor with at least one connection member leading from each anchor,

and each of the connection members is be bound to at least one other connection member.

Any of the devices described herein can be used for closing defects in the AF whether created surgically or during the herniation event. Such methods may also involve the addition of biocompatible material to either the AF or NP. This material could include sequestered or extruded segments of the NP found outside the pre-herniated borders of the disc.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered illustrative and not restrictive, the scope of the invention being dictated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

Claims

I claim:

1. An *in vivo* augmented functional spine unit comprising:

a) a first vertebra having an anterior end and a posterior end;

b) a second vertebra having an anterior end and a posterior end; said second vertebra adjoining said first vertebra, forming an intervertebral space between said first and said second vertebra, said anterior end of said first vertebra aligned with said anterior end of said second vertebra, and said posterior end of said first vertebra aligned with said posterior end of said second vertebra;

c) an intervertebral disc having an anulus fibrosis surrounding a central region, said intervertebral disc positioned between said first and second vertebra within the intervertebral disc space; and

d) a disc herniation constraining device including an anchor, a support member, and a connection member coupled therebetween; said anchor being fixedly coupled to an anterior portion of one of said first vertebra or said second vertebra or anulus fibrosis, and said support member coupled to a portion of said anulus fibrosis in a position posterior to said central region; and said connection member extending between said anchor and said support member whereby said connection member is maintained between said anchor and said support member.

2. The *in vivo* augmented functional spine unit of claim 1 wherein augmentation material is disposed along at least a portion of said connection member within the intervertebral disc space.

3. The *in vivo* augmented functional spine unit of claim 1 wherein the connection member is maintained under tension between said support member and said anchor.

4. The *in vivo* augmented functional spine unit of claim 1 further comprising nucleus pulposus in said central region .

5. An *in vivo* augmented functional spine unit comprising:

a) a first vertebra having an anterior end and a posterior end;

b) a second vertebra having an anterior end and a posterior end; said second vertebra adjoining said first vertebra, forming an intervertebral space between said first and said second vertebra, said anterior end of said first vertebra aligned with said anterior end of said second vertebra, and said posterior end of said first vertebra aligned with said posterior end of said second vertebra;

c) an intervertebral disc having an anulus fibrosis surrounding a central region pulposus, said intervertebral disc positioned between said first and second vertebra substantially within the intervertebral disc space; and

d) a disc augmentation device including an anchor, augmentation material, and a connection member coupled therebetween; said anchor being fixedly coupled to an anterior portion of one of said first veterbra or said second vertebra or anulus fibrosis, and said augmentation material positioned in said intervertebral disc space between said adjacent vertebra; and said connection member extending between said anchor and said augmentation material whereby said connection member restrains movement of said augmentation material to be substantially within said intervertebral disc space.

6. The *in vivo* augmented functional spine unit of claim 5 wherein said connection member extends between said anchor and a support member, said support member being positioned in a portion of the functional spine unit opposite said anchor, whereby movement of said augmentation material is further restrained within said intervertebral disc space.

7. The *in vivo* augmented functional spine unit of claim 4 further comprising nucleus pulposus in said central region.

8. An invasive method of treating a herniated intervertebral disc involving the displacement of all or part of the herniated segment away from compressed nerve structures without removal of the segments.

9. An invasive method of treating a herniated intervertebral disc involving the displacement of all or part of the herniated segment to within the pre-herniated borders of the disc.

10. A method of repairing a herniated IV disc involving anchoring at least a portion of the herniated segment or surrounding anulus fibrosus to a site in the involved functional spinal unit.

11. A method of repairing a herniated IV disc involving the steps of

a) displacing at least a portion of the herniated segment to within the pre-herniated borders of the disc

b) anchoring at least a portion of the displaced herniated segment or surrounding anulus fibrosus to a site in the involved functional spinal unit.

12. A method of treating a herniated intervertebral disc involving the steps of

a) establishing a first anchoring means in at least a portion of the herniated segment of disc or surrounding anulus fibrosus

b) establishing a second anchoring means in a site in the involved functional spinal unit

c) providing at least one connection means which joins the first and second anchoring means

d) applying tension between the first and second anchoring means along the connection means to cause the herniated segment or surrounding anulus fibrosus to move within the pre-herniated borders of the disc.

13. A method of treating a herniated intervertebral disc involving the steps of

a) establishing a first anchoring means in or just posterior to at least a portion of the herniated segment of disc or surrounding anulus fibrosus

b) establishing a second anchoring means anterior to the herniated segment

c) providing a connection means which joins the first and second anchoring means

d) applying tension between the first and second anchoring means along the connection means to cause the herniated segment or surrounding anulus fibrosus to move anteriorly.

14. A method of supporting a weakened section of the anulus fibrosus of an intervertebral disc involving the step of attaching the weakened section to another portion of the functional spinal unit removed from said weakened section.

15. A method as described in claims 11, 12, 13 or 14 further involving the insertion of biocompatible material into the disc space to aid in restoring disc height.

16. A method as described in claims 11, 12, 13 or 14 wherein said site is either the superior or inferior vertebral body.

17. A method as described in claims 11, 12, 13 or 14 wherein said site is the anterior, anterior medial or anterior lateral anulus fibrosus.

18. A method of augmenting the nucleus pulposus of the intervertebral disc involving the steps of

a) providing a first anchoring means in a site in the involved functional spinal unit

b) providing at least one connection means leading from said anchoring means that at least in part traverses the disc space

c) inserting into the disc space at least one plug of biocompatible material on said connection means

d) terminating said connections means so as to prevent said plug or plugs from moving off said connection means and/or out of said disc space.

19. A method as described in claim 18 in which said connection means is terminated by using it to close an opening in the anulus fibrosus.

20. A method as described in claim 18 wherein terminating the connection means involves the steps of affixing a second anchoring means to the connection means and further affixing said second anchoring means to a site in the involved FSU.

21. A method as described in claim 19 wherein said connection means is terminated by a capping means that is affixed to the connection means.

22. A method as described in claim 19 wherein said connection means is terminated by connecting the un-terminated end of the connection means back to the first anchoring means.

23. A method as described in claims 11, 12, 13, 14, or 18 further involving the step of applying tension along said connection means between said first anchor means and said second anchoring means, the closed anulus fibrosus, or cap.

24. A method as described in claim 12 wherein said plug or plugs are movably affixed to said connection means so as to be insertable into the disc space along said connection means after placement of said first anchoring means and prior to terminating the connection means.

25. A method of augmenting the nucleus pulposus of the intervertebral disc involving the steps of

a) Inserting a biocompatible material into the disc space, said material being attached to an anchoring means

b) Anchoring said material to a site within the FSU with said anchoring means.

26. A method of augmenting the nucleus pulposus of the intervertebral disc involving the anchoring of a biocompatible material to an anterior, anterior medial, anterior lateral, or lateral portion of the anulus fibrosus.

27. A method as described in claims 25 wherein said material is a fibrous material including either collagen or cellulous.

28. A method as described in claims 25 wherein said material is herniated nucleus pulpous found exterior to the confines of the disc.

29. A method as described in claims 11, 12, 13, 14, 18, or 25 further involving the step of closing a defect in the anulus fibrosus.

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (b)) - INDEPENDENT INVENTOR	Docket No. LAML-110PR

Serial No.	Filing Date	Patent No.	Issue Date

Applicant/ Patentee: Gregory H. Lambrecht

Invention: DEVICES AND METHODS OF INTERVERTEBRAL DISC AUGMENTATION

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled above and described in:

- ☒ the specification to be filed herewith.
- ☐ the application identified above.
- ☐ the patent identified above.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ No such person, concern or organization exists.
- ☐ Each such person, concern or organization is listed below.

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

FULL NAME Gregory H. Lambrecht
ADDRESS 220 Eliot Street, Natick, MA 01760
☒ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR Gregory H. Lambrecht
SIGNATURE OF INVENTOR [signature] DATE: 8/18/99

NAME OF INVENTOR ____
SIGNATURE OF INVENTOR ____ DATE: ____

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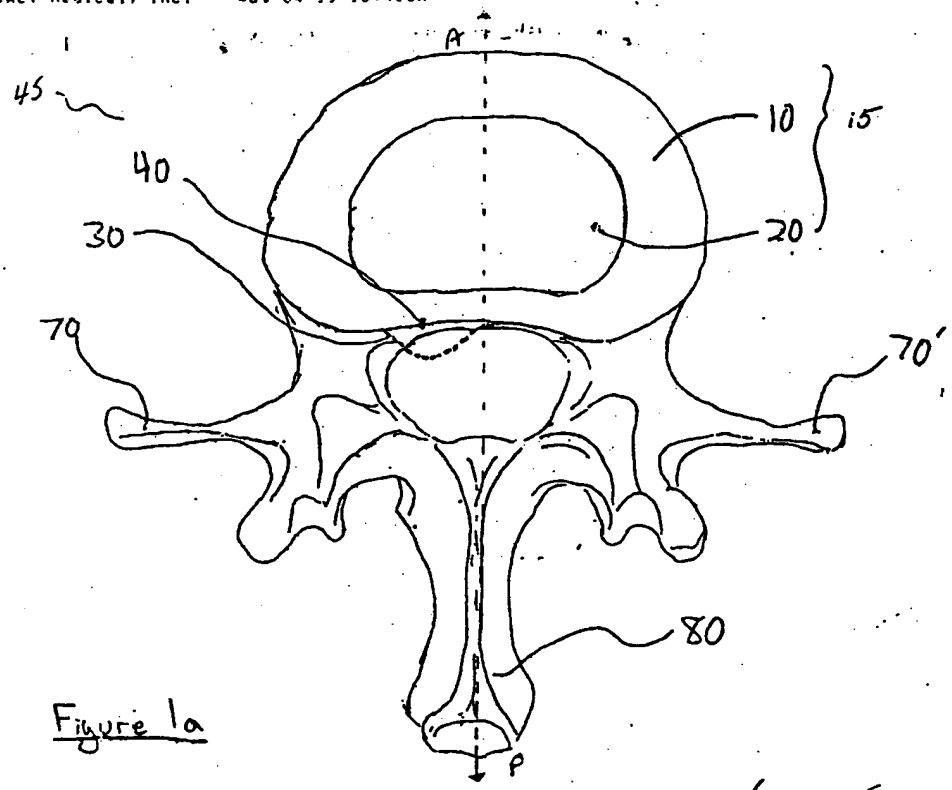

Figure 1a

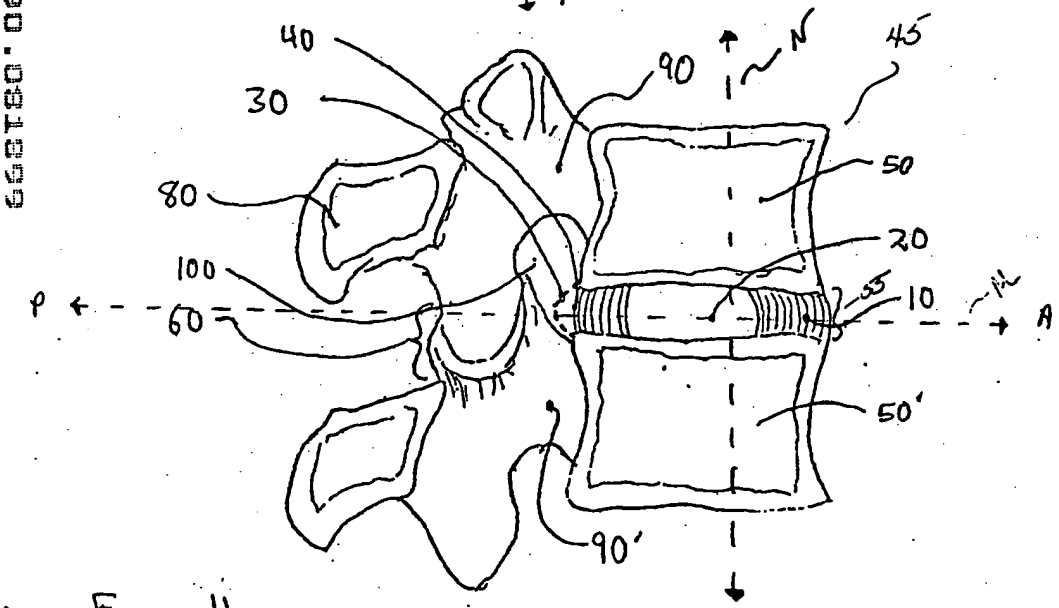

Figure 1b

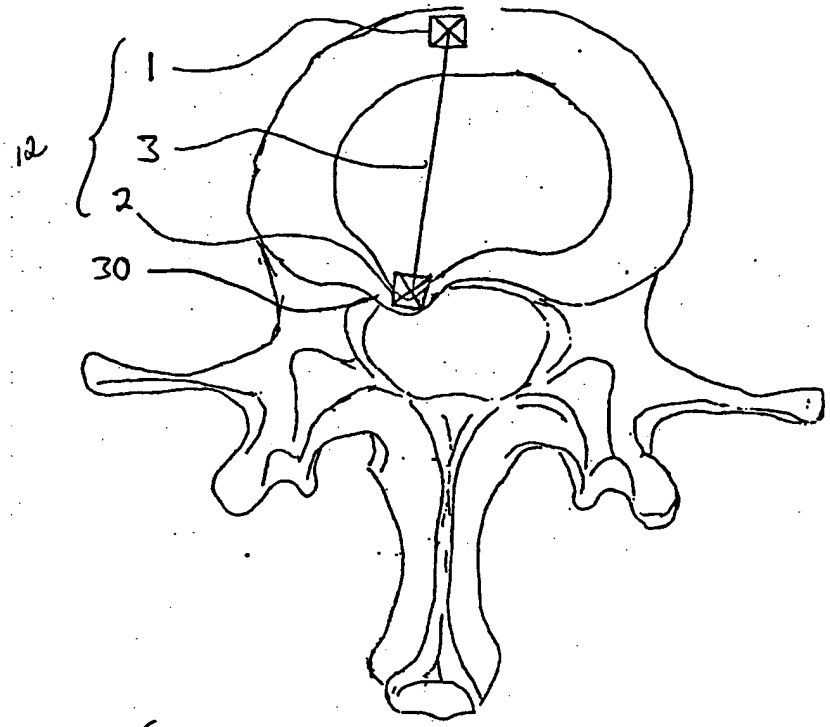

Figure 2a

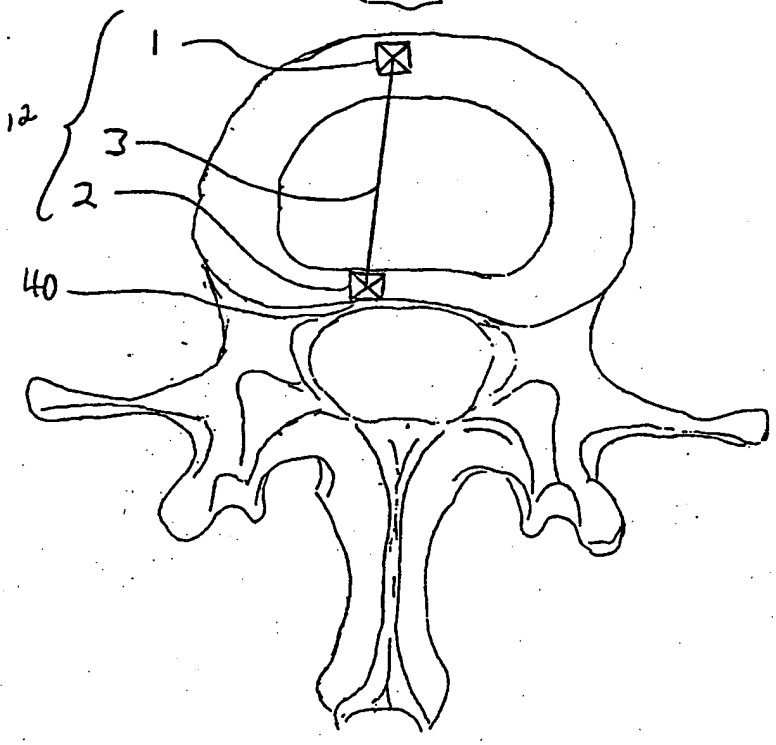

Figure 2b

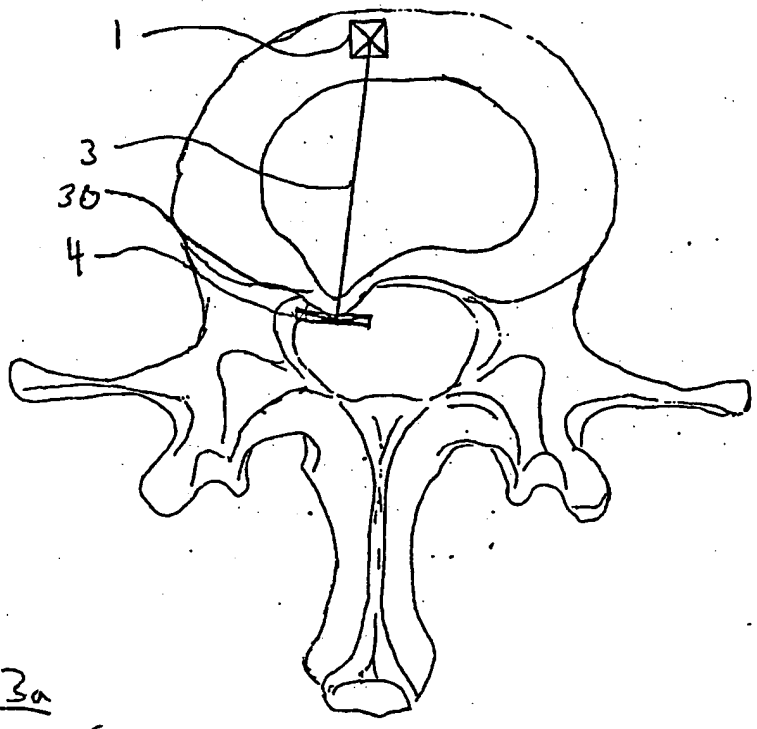

Figure 3a

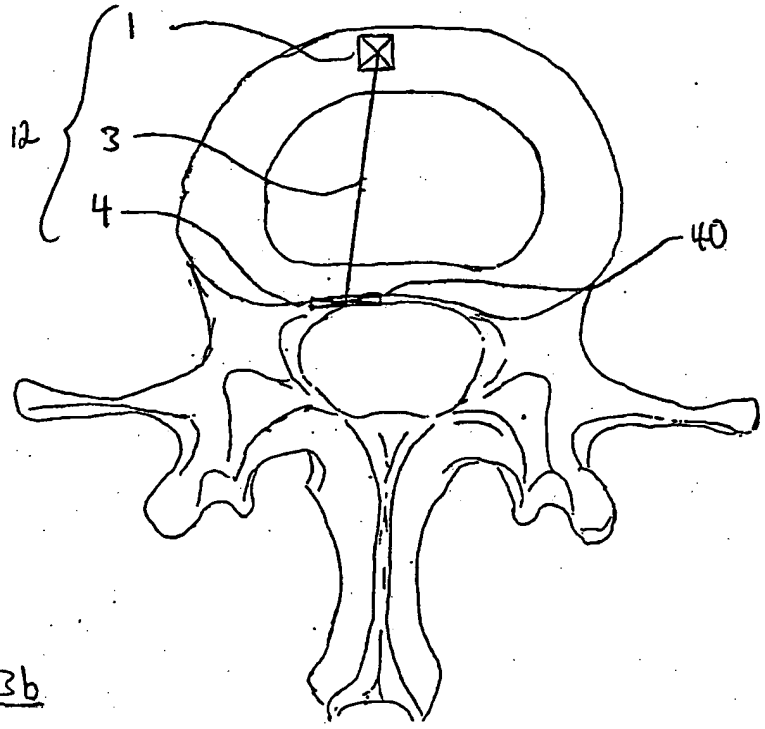

Figure 3b

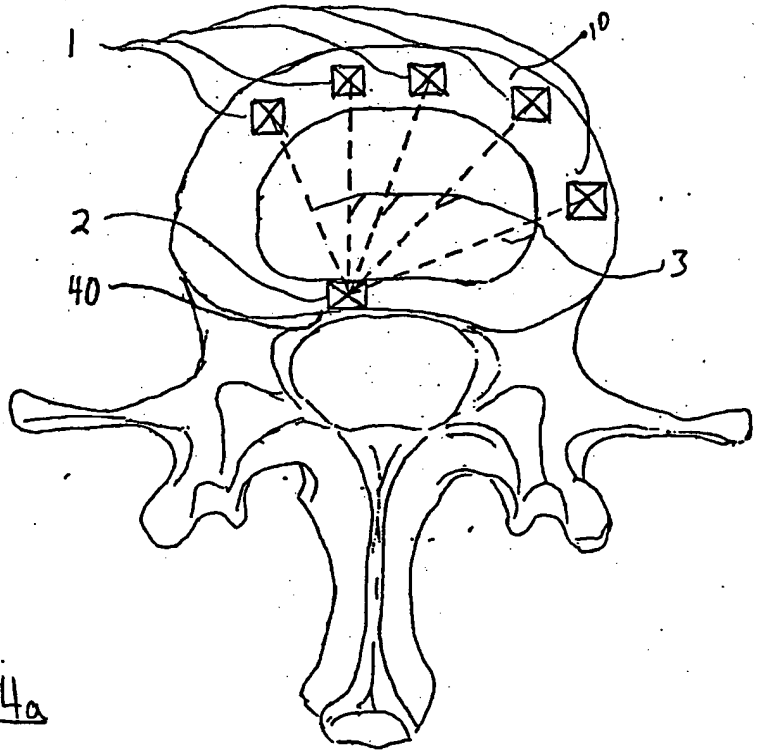

Figure 4a

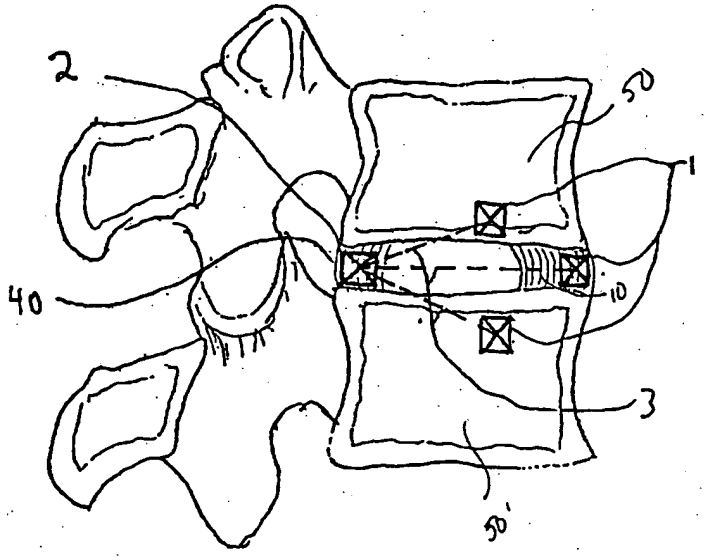

Figure 4b

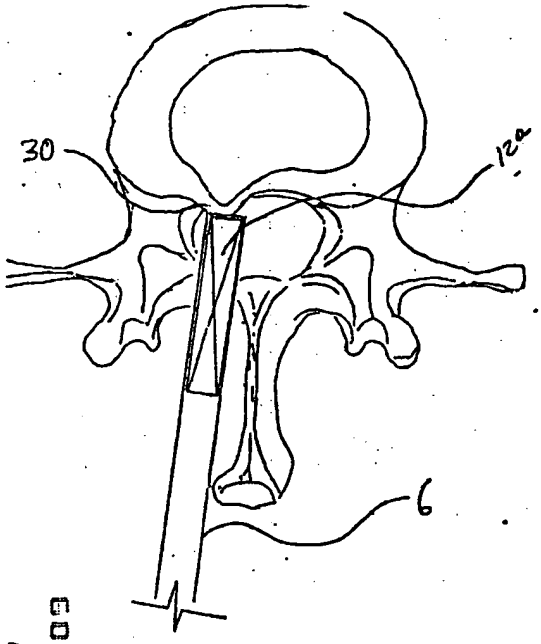

Figure 5a

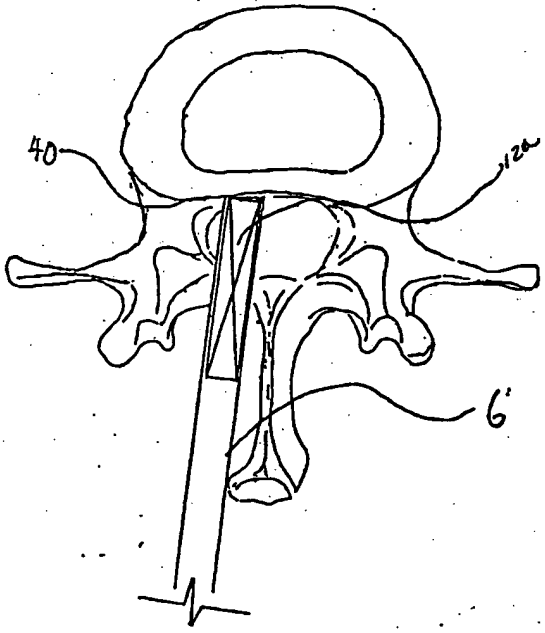

Figure 5b

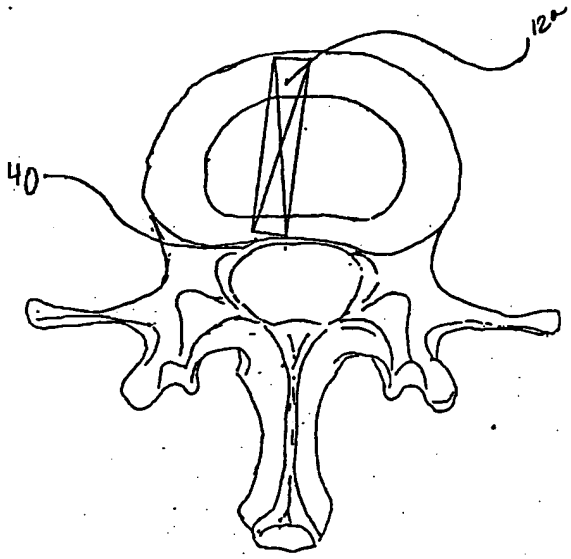

Figure 5c

Figure 6

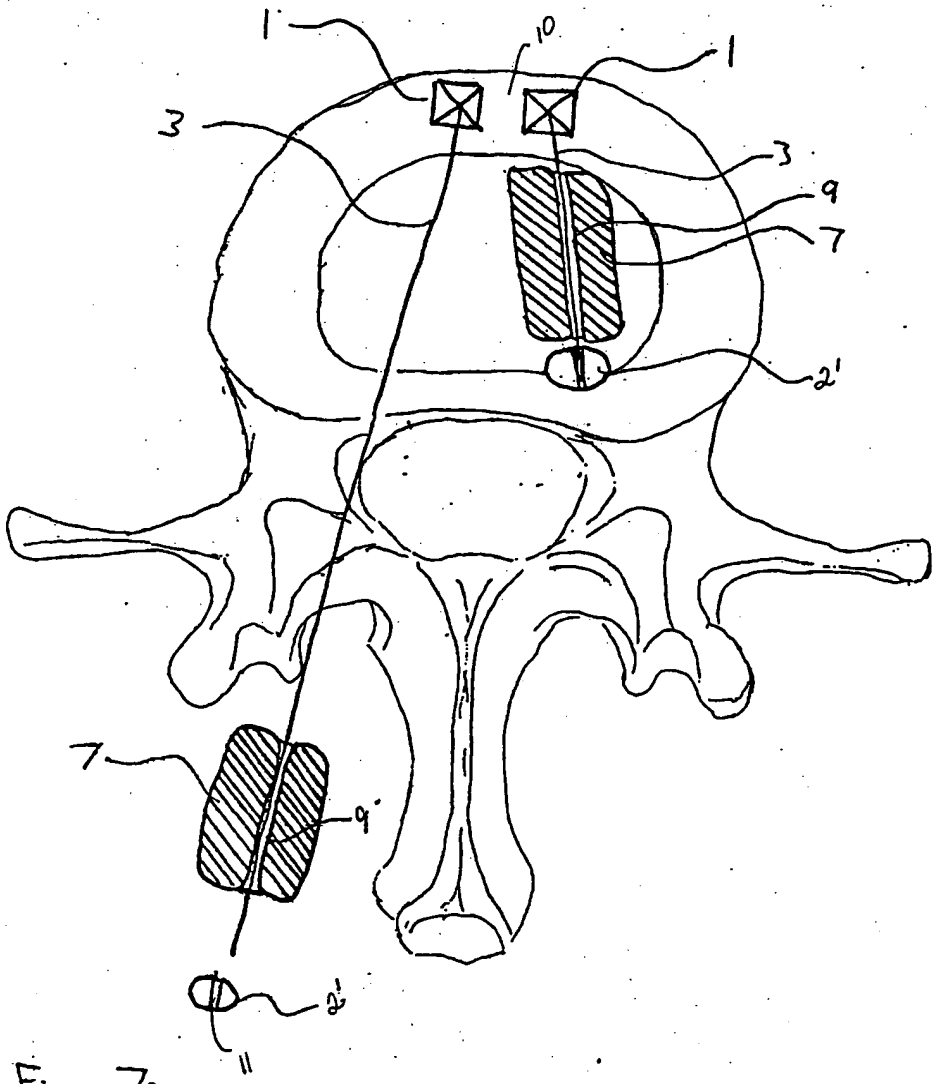

Figure 7A

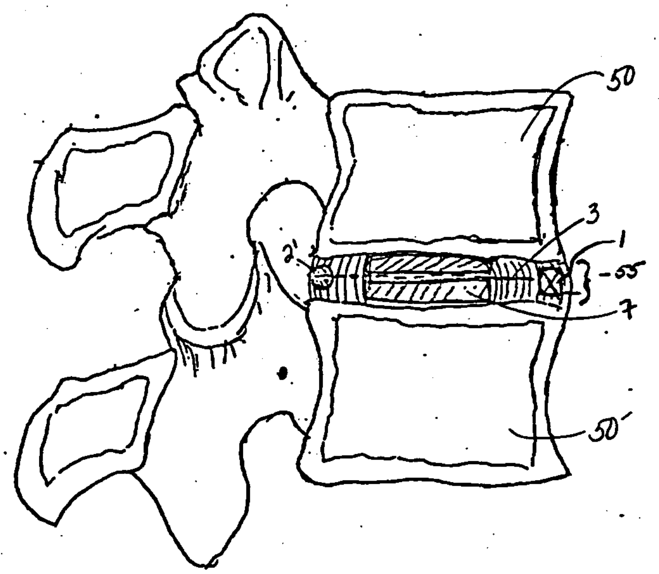

Figure 7B

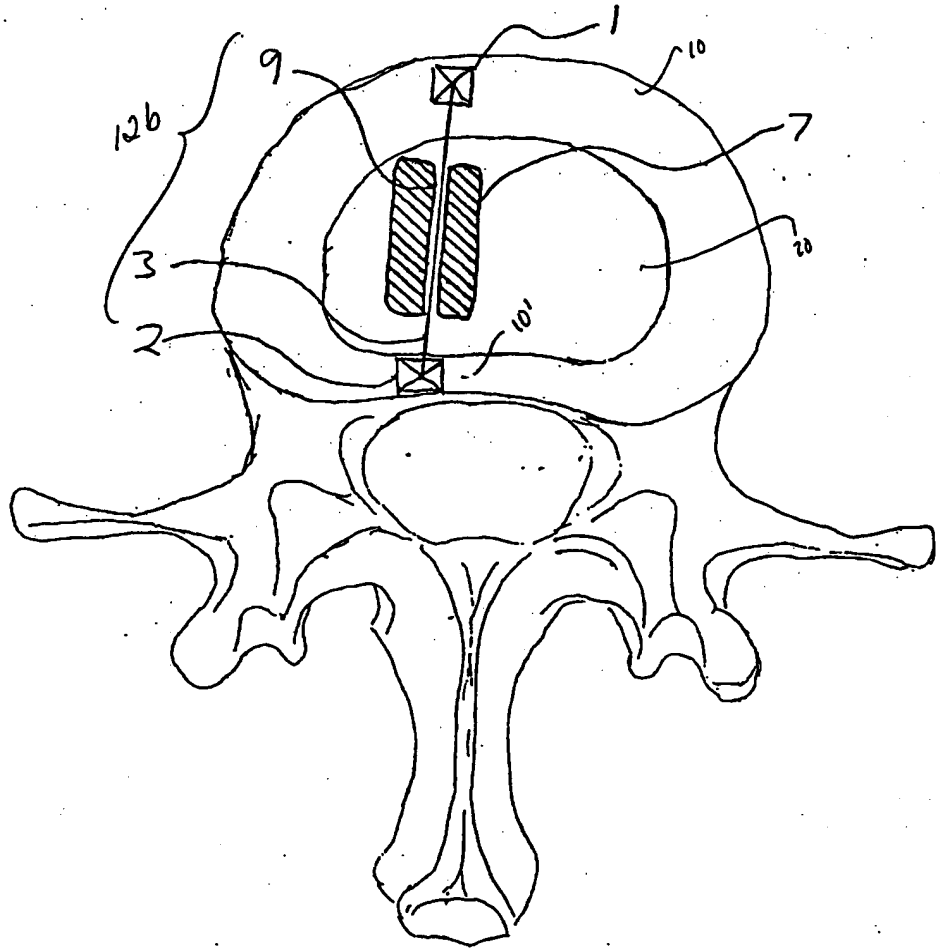

Figure 8

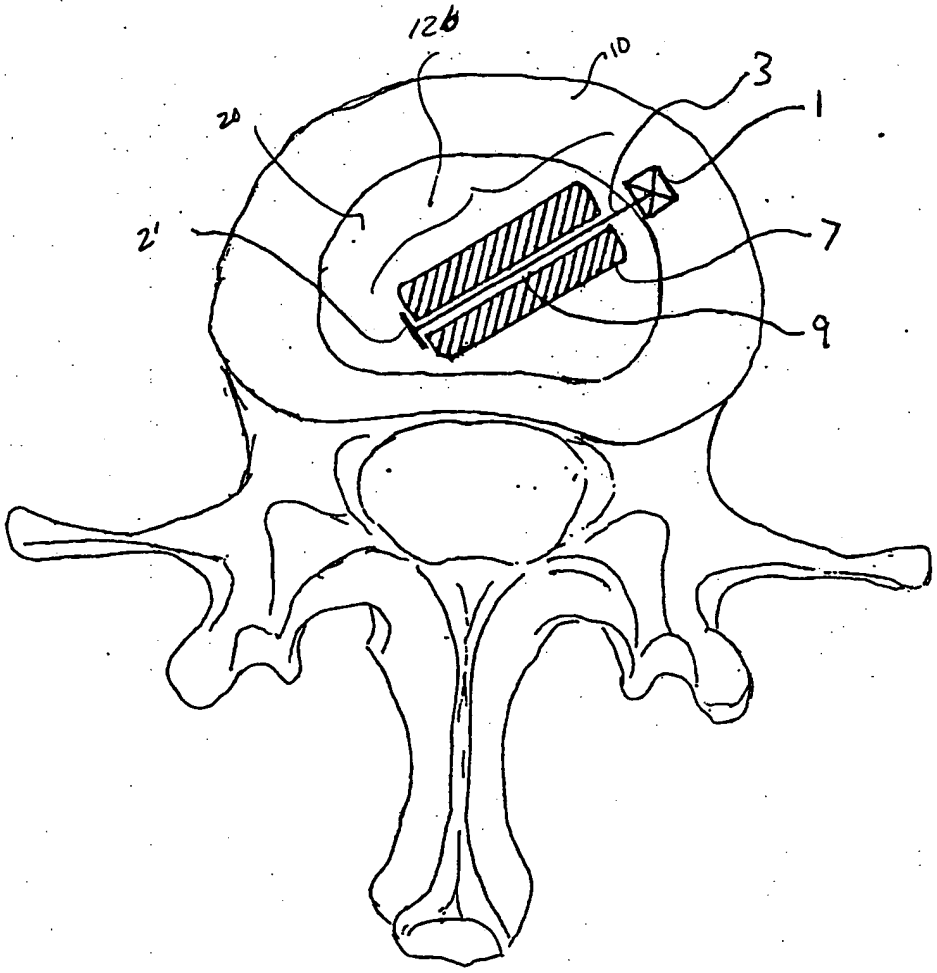

Figure 9a

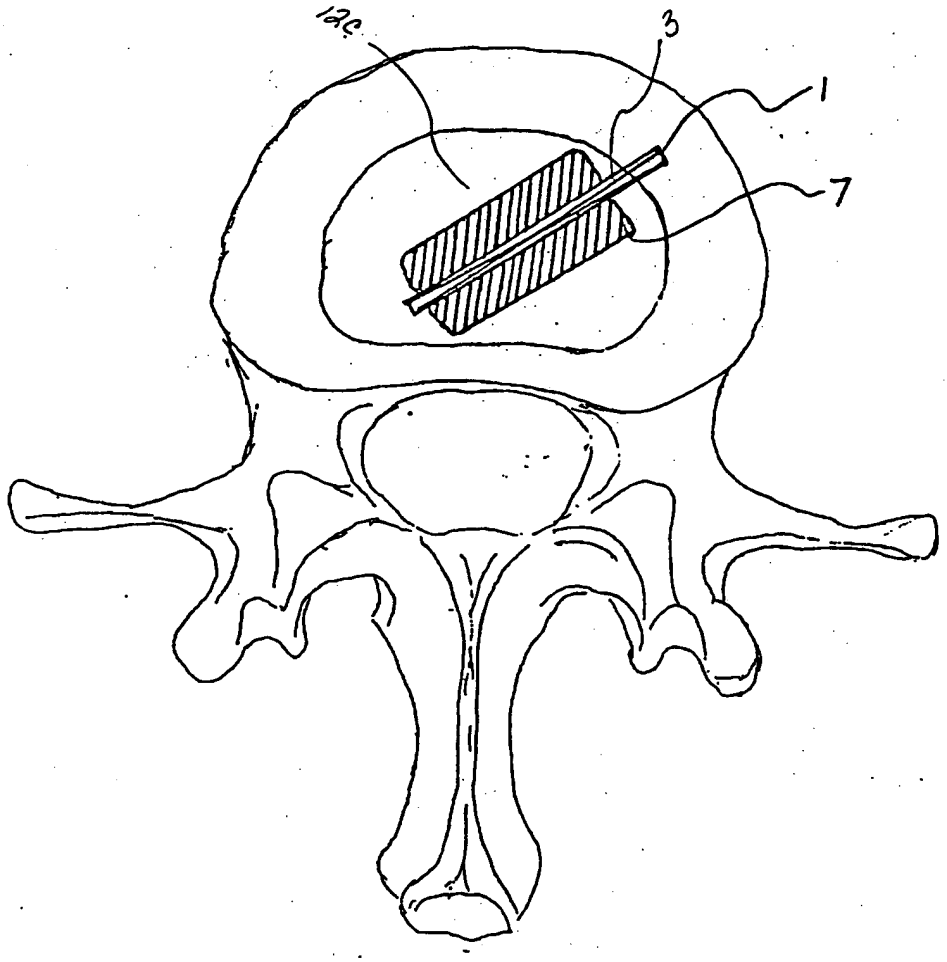

Figure 9b

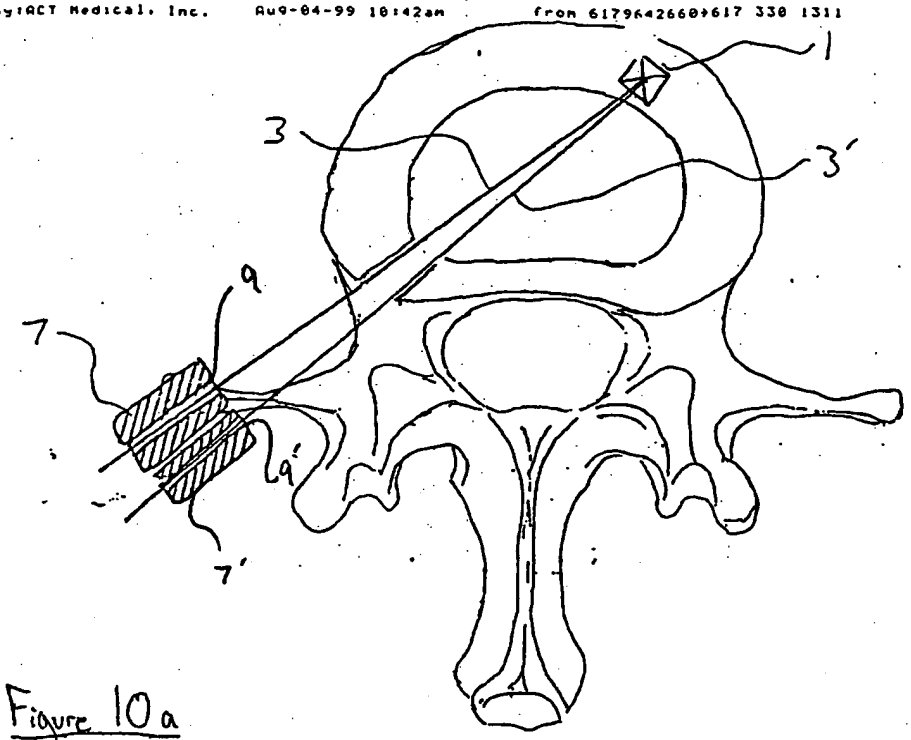

Figure 10a

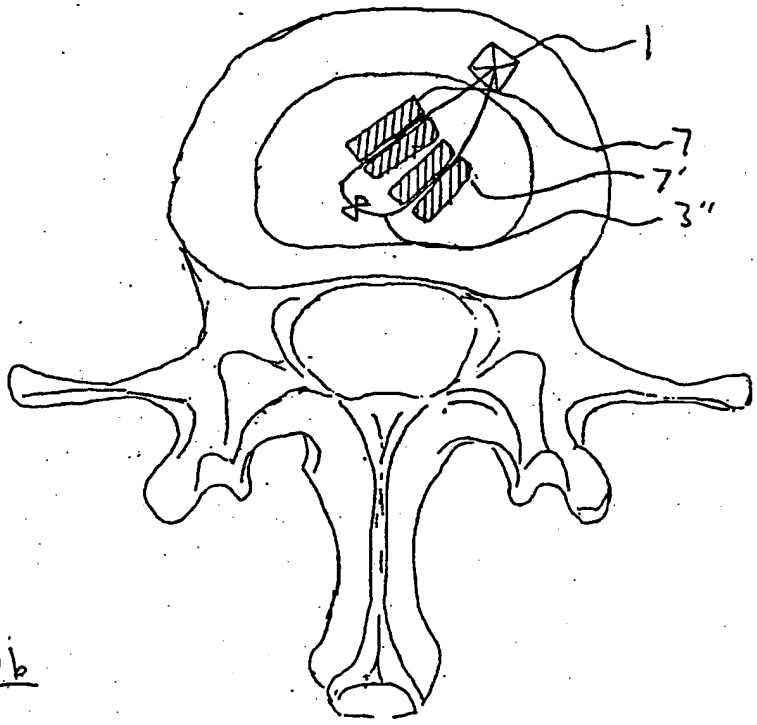

Figure 10b

TO:USPTO
12/18/00

PATENT APPLICATION
Docket No 3005.1000-005
3005.1000-006
3005.1000-007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gregory H. Lambrecht
U.S Application No.: 60/149,490
Filed: August 18, 1999
Title: DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.: 3005.1000-005

Applicants: Gregory H. Lambrecht
U S Application No.: 60/161,085
Filed: October 25, 1999
Title: DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.: 3005.1000-006

Applicants: Gregory H. Lambrecht
U.S. Application No.: 60/172,996
Filed: December 21, 1999
Title: DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No : 3005.1000-007

POWER OF ATTORNEY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

As a named inventor, I hereby appoint the attorneys and/or agents associated with Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Drive, Lexington, Massachusetts 02421-4799, Customer No. 21005, to prosecute the above-identified applications and to transact all business in the Patent and Trademark Office connected therewith.

Please send all correspondence to Thomas O. Hoover, Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Drive, Lexington, MA 02421-4799. Please direct all telephone calls to Thomas O. Hoover at (781) 861-6240.

Respectfully submitted,

By_____
Gregory H. Lambrecht

Date. 12/18/2003

PTO/SB/58 (11-88)
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REQUEST FOR ACCESS OF ABANDONED APPLICATION UNDER 37 CFR 1.14(a)

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In re Application of	
Application Number: 60/149,490	Filed: 8/18/99
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I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

1 (A) referred to in United States Patent Number 6,425,919, column Face.

___ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. _____, filed _____, on page _____ of paper number _____,

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US006425919B1

(12) **United States Patent**
Lambrecht

(10) **Patent No.: US 6,425,919 B1**
(45) **Date of Patent: Jul. 30, 2002**

(54) **DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION**

(75) Inventor: **Gregory H Lambrecht**, Natick, MA (US)

(73) Assignee: **Intrinsic Orthopedics, Inc.**, Wilmington, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1 day.

(21) Appl. No.: **09/608,797**

(22) Filed: **Jun. 30, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/140,490, filed on Aug. 18, 1999; provisional application No. 60/161,085, filed on Oct. 25, 1999, and provisional application No. 60/172,996, filed on Dec. 21, 1999.

(51) Int. Cl.[7] **A61F 2/44**
(52) U.S. Cl. **623/17.16**
(58) Field of Search 623/17.16; 128/898

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,140,452	A *	10/2000	Felt et al.	528/60
6,224,630	B1	5/2001	Bao et al.	
6,245,107	B1 *	6/2001	Ferree	623/17

FOREIGN PATENT DOCUMENTS

WO	9981084	12/1999
WO	WO 00/62832	10/2000
WO	0110318	2/2001
WO	WO 01/21246 A1	3/2001
WO	0128464	4/2001

* cited by examiner

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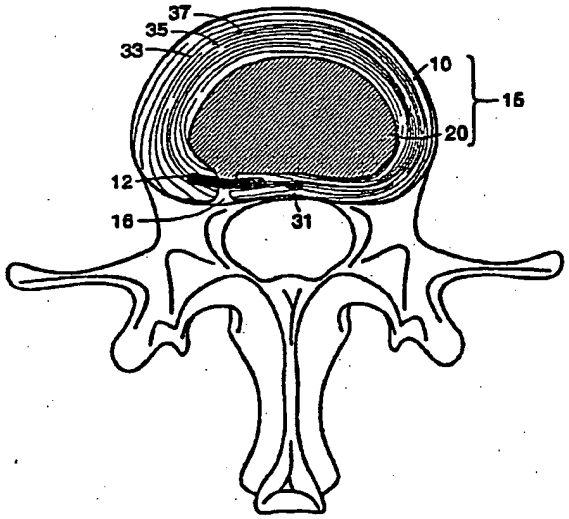
(57) **ABSTRACT**

A disk herniation constraining device for implantation into a vertebral disk can include a support member for support of a herniated portion of a disk. The support member can be connected to an anchor. The constraining device can include the insertion of augmentation material within the disk. A defect in the annulus of a disk can be closed using a prosthesis such as a barrier.

The barrier can be placed between the annulus and the nucleus of the disk. The barrier can include a sealant and an enlarger. The barrier can be implanted into the disk using a delivery cannula, an advancer and at least one control filament to control the positioning of the barrier over the defect. A stiffening element can be included within the barrier to impart stiffness to the barrier.

20 Claims, 64 Drawing Sheets



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